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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4202]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use—Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Form FDA 356h (OMB Control Number 0910–0338)—Extension

FDA is the Federal agency charged with the responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, or biologic for human use must file applications for FDA approval of the product prior to introducing it into interstate commerce. Statutory authority for the collection of this information is provided by section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j)) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Manufacturers of new drugs for human use regulated under the act must submit a new drug application (NDA) for review and approval to the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER) prior to marketing a drug in interstate commerce (§ 314.50 (21 CFR 314.50)). Manufacturers of generic drugs regulated under the act must submit an abbreviated new drug application (ANDA) for review and approval to CDER prior to marketing a generic drug in interstate commerce (§ 314.94 (21 CFR 314.94)). Manufacturers of biological products regulated under the PHS Act must submit an establishment license application (ELA) and a product license application (PLA) or biologics license application (BLA) for review and approval to CBER prior to marketing a biological product in interstate commerce (§ 601.2 (21 CFR 601.2)). Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Applicants are required to report to FDA any transfer of ownership of an NDA (21 CFR 314.72). Applicants are required to report a change in ownership of an ANDA (21 CFR 314.99(a)). Manufacturers of a drug or biologic for human use are required to file supplemental applications for certain changes to applications previously approved (§§ 314.70, 314.71, 314.97, and 601.12 (21 CFR 314.70, 314.71, 314.97, and 601.12)). The form is also submitted with an amendment to an unapproved original application or supplemental application,

and a presubmission or resubmission of information pertaining to an application. The information provided by manufacturers with the application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs and biologics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filling out a drug application and has been previously used only by manufacturers of products regulated under the act. In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of the revised Form FDA 356h. The form was revised as a ''Reinventing Government'' initiative to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form provides key information to the agency for efficient handling and distribution to the appropriate staff for review. For biologics manufacturers, the form will replace a number of different ELA and PLA forms that were formerly used for these products. The information collection burden for various ELA and PLA forms is covered under OMB Control No. 0910–0124. There are an estimated 343 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The annual responses are based on submissions received by FDA in 1998. The time estimated to prepare an ELA, PLA, or BLA under § 601.2 for CBER approval to market a new product is based on information provided by industry. The time required for preparing an ELA, PLA, or BLA includes the estimate for filling out the form. The estimated average burden hours for the other submissions using Form 356h to CBER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The average burden hours also include the time to prepare an amendment submitted to CBER. The estimated burden hours to prepare a supplement to CBER (§ 601.12) are reported under OMB Control No. 0910–0315.

In the **Federal Register** of October 21, 1999 (64 FR 56797), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS[1]

21 CFR Section/FDA Form	No. of Respondents	Total Annual Responses	Hours per Response	Total Hours
601.2	343	84	1,600	134,400
Form FDA 356h	343	4,947	16	79,152
Total				213,552

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

There are 483 drug applicants that submitted the form. The annual responses are based on submissions received by FDA in 1997 and 1998. The estimated average burden hours for the submissions using Form 356h to CDER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The estimated burden hours to prepare an NDA (§ 314.50); an ANDA (§ 314.94); supplements (§§ 314.70, 314.71, and 314.97); and amendments (21 CFR 314.60 and 314.96) are approved under OMB Control No. 0910–0001.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS[1]

FDA Form	No. of Respondents	Total Annual Responses	Hours per Response	Total Hours
Form FDA 356h	483	16,221	24	389,304
Total				389,304

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 24, 2000

William Hubbard

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

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